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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC., et al., **Plaintiffs,** **v.** **ROXANE LABORATORIES, INC.,** **Defendant.**	**Civil Action No. 15-1360 (ES)(JAD)** **(Filed Electronically)**

JAZZ PHARMACEUTICALS' OPENING *MARKMAN* BRIEF

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Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Jazz") submit this brief in support of their proposed constructions of the disputed terms of United States Patent Nos. 8,461,203 ("the '203 patent"), 8,859,619 ("the '619 patent"), and 8,952,062 ("the '062 patent") (collectively, the "'431 patent family"), and 8,772,306 ("the '306 patent") and 9,050,302 ("the '302 patent") (collectively, the "'306 patent family") owned by Jazz (collectively, "the patents-in-suit").

I. INTRODUCTION

The five patents-in-suit discussed in this briefing belong to two patent families. The first family—the '431 patent family—covers pharmaceutical compositions of sodium oxybate and methods of using sodium oxybate to treat narcolepsy, a debilitating sleep disorder. There are two disputed terms concerning these patents. The second family—the '306 patent family—covers methods of treating certain sleep disorders in patients with reduced dosages of gamma-hydroxybutyrate ("GHB"), when GHB is co-administered with valproate, also known as valproic acid or divalproex sodium. There is one disputed term concerning these patents.

For the two disputed terms from the '431 patent family, Jazz proposes that no construction is necessary. These two disputed terms consist of easily understandable, non-technical language whose meaning is readily apparent to a person of ordinary skill in the art. Consistent with the Federal Circuit's controlling guidance in *Phillips* and its progeny, the terms' plain and ordinary meaning should apply. For the remaining term in dispute from the '306 patent family, Jazz merely seeks to apply the inventor's lexicography. This approach follows the well-established principle that the inventor's lexicography governs, as stated in *Phillips*.

By contrast, Roxane's proposed constructions violate bedrock principles of claim construction because they: (1) seek to read limitations into the claims; and (2) ignore the

inventor's lexicography. All of Roxane's proposed constructions are litigation-driven, have no basis in the intrinsic record, and should be rejected.

II. BACKGROUND

A. XYREM®

Jazz is a specialty pharmaceutical company. It markets the drug product XYREM® to treat patients with two of the most prevalent symptoms of narcolepsy – excessive daytime sleepiness and cataplexy. Narcolepsy is a sleep disorder that affects about 150,000 to 200,000 patients in the United States. All patients with narcolepsy suffer from excessive daytime sleepiness, which is so overpowering that it results in involuntary sleep attacks while the patient is engaged in everyday activities such as talking, walking, eating, standing, and driving. Narcolepsy patients also commonly suffer from cataplexy, a condition manifested by episodes of loss of muscle control leading to the patient collapsing. Cataplexy can be triggered by emotional responses such as laughter, anger, embarrassment, or surprise. Most people with narcolepsy also suffer from irregular sleep patterns that cause some of narcolepsy's symptoms.

B. The '431 Patent Family

XYREM is sold as a concentrated oral solution that is diluted by the patient with water prior to its use at bedtime. Under certain conditions, the active ingredient in XYREM, sodium oxybate (a/k/a GHB), may become chemically unstable and break down. GHB solutions may also become prone to microbial contamination. The inventors of the '431 patent family developed pharmaceutical compositions of GHB that are chemically stable and microbial resistant, without the need for a preservative. Jazz's claims in the '431 patent family cover such novel pharmaceutical compositions, and also methods of making and using the novel pharmaceutical compositions. The Court previously construed eight terms from the first group of patents in the '431 patent family in the matter *Jazz Pharmaceuticals, Inc. v. Roxane*

Laboratories, Inc., Civ. No. 10-6108, D.I. 151 (ES) (JAD) ("Civ. No. 6108").[1] There, the Court rejected Roxane's attempts to import unsupported limitations into the claims. (*See, e.g., id.* at 9, 22, and 23-24 (construing "adding," "organic acid," and "dose," respectively).)

C. The '306 Patent Family

The '306 patent family claims specific methods of treating certain sleep disorders in patients receiving both GHB and valproate. Valproate is used as an anticonvulsant and mood-stabilizing drug, primarily in the treatment of epilepsy and bipolar disorder. In addition to its central nervous system effects, valproate can also inhibit certain biological processes that have the potential to affect GHB levels in the patient's body. Specifically, valproate is involved in processes that can both raise or lower the levels of GHB in the patient. The '306 patent family claims methods for safely co-administering GHB and valproate to treat patients with sleep disorders such as cataplexy and excessive daytime sleepiness. The Court has not previously construed any terms in the '306 patent family.

D. Defendant

Defendant Roxane is a generic pharmaceutical company. Roxane filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to market a generic copy of Jazz's XYREM product. Jazz alleges, among other things, that Roxane's generic copy of XYREM would infringe certain claims of the patents-in-suit addressed in this briefing.

III. LEGAL STANDARD

Claim construction is an issue of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995). The Federal Circuit has explained that claim construction starts with the words of the claims. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294,

[1] The other patents in the '431 patent family are U.S. Patent Nos. 6,472,431 ("the '431 patent"), 6,780,889, 7,262,219, 7,851,506, 8,263,650, and 8,324,275.

1298 (Fed. Cir. 2003). Claim terms are deemed to be read "not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). If the patentee has specifically defined a claim term in the specification, that definition controls. *Id.* at 1316 ("[T]he inventor's lexicography governs."). When the patentee has not provided an explicit definition of a claim term, however, the words of a claim are given their plain and ordinary meaning to a person of ordinary skill in the art. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Indeed, "[a]bsent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language." *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004).

IV. ARGUMENT

The patents-in-suit generally fall into two categories: (1) pharmaceutical compositions containing sodium oxybate and related methods of making and using the same claimed in the '431 patent family; and (2) methods of safely treating patients who are receiving both sodium oxybate and valproate claimed in the '306 patent family. The parties dispute the meaning of three terms in the asserted claims of the patents-in-suit.

A. The '431 Patent Family

The '203, '619, and '062 patents claim pharmaceutical compositions containing sodium oxybate and methods of making and using such compositions. The parties dispute two terms in those patents, as discussed below.

1. "Admix"

The disputed claim terms "admixing" and "admixed" appear in claims 1, 7, and 8 of the '203 patent. Claims 1, 7, and 8 state (with emphasis on the disputed claim terms):

> 1. A method of rendering an aqueous medium resistant to microbial growth, said method comprising **admixing a salt of gamma hydroxybutyrate with the aqueous medium**, adjusting the concentration of the gamma-hydroxybutyrate salt in the aqueous medium to a final concentration of from about 310 to about 750 mg/ml, and adjusting the pH of the medium to a final pH of about 6 to about 9, so that the medium is chemically stable and resistant to microbial growth, wherein the medium would not need to contain a preservative.
>
> 7. The method of claim 1, **wherein the components are admixed sequentially**.
>
> 8. The method of claim 1, **wherein the components are admixed simultaneously**.

The parties' proposed constructions are as follows:

"admix"		
Phrase	**Jazz's construction**	**Roxane's construction**
"admixing a salt of gamma hydroxybutyrate with the aqueous medium"	No construction necessary.	"adding a salt of gamma hydroxybutyrate to an aqueous medium, and then mixing the resulting medium"
"wherein the components are admixed sequentially"	No construction necessary.	"wherein a salt of gamma-hydroxybutyrate is first added to an aqueous medium and the resulting medium is then mixed"
"wherein the components are admixed simultaneously"	No construction necessary.	"wherein a salt of gamma hydroxybutyrate is added to an aqueous medium, and the resulting aqueous medium is mixed at the same time"

The term "admix" requires no construction. Claim construction "is not an obligatory exercise in redundancy." *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). Despite this, Roxane seeks to import limitations into the otherwise readily understandable term "admix." Specifically, Roxane's constructions read in the limitations "adding a salt of gamma hydroxybutyrate to an aqueous medium," "mixing the resulting

medium," "a salt of gamma-hydroxybutyrate is first added to an aqueous medium," "the resulting medium is then mixed," "a salt of gamma hydroxybutyrate is added to an aqueous medium," and "resulting aqueous medium is mixed at the same time." There is nothing in the claims or specification of the '203 patent that requires the gamma hydroxybutyrate to be pre-made and then added to the aqueous medium as Roxane's constructions suggest.

As an initial matter, Roxane seeks to read sequential "adding …. then mixing" steps into the phrase "admixing a salt of gamma hydroxybutyrate with the aqueous medium" from independent claim 1 of the '203 patent. But claims 7 and 8, which depend from claim 1, have contrary additional limitations that the admixing occur "sequentially" or "simultaneously." Thus, under Roxane's proposed construction, claim 8 would be outside of the scope of claim 1 from which it depends. This is improper. *See AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003) ("dependent claims are presumed to be of narrower scope than the independent claims from which they depend"). Roxane's proposed constructions should be rejected for this reason alone.

Furthermore, the '203 patent specification refers to an "amount of GHB added, admixed, or dissolved" in an aqueous medium. (Ex. 1, '203 patent at 4:17.)[2] It appears that Roxane is attempting to define "admixing" as dissolving pre-made gamma hydroxybutyrate in an aqueous medium when that is explicitly described as something different in the specification.

Roxane's argument here is similar to its prior attempt in the previous *Markman* briefing to limit the term "adding" in the parent to the '203 patent (the '431 patent) to mean "externally adding a pre-made gamma-hydroxybutyrate salt into a pre-existing aqueous medium." This Court rejected Roxane's attempt to limit the claims, finding that

[2] "Ex. __" herein refers to the exhibits to the Declaration of Gabriel P. Brier in support of Jazz's Opening *Markman* Brief.

> The Court rejects this argument because Roxane points to nothing in the intrinsic evidence that requires the salt to be pre-formed and added from an external location. The fact that the patent describes the salt being "mixed or dissolved" does not mean the salt has to come from outside the aqueous solution.

(Ex. 2, Civ. No. 10-6108, D.I. 151 at 9.) Here, the specification of the '203 patent is the same as the '431 patent and the record has not changed. As the Court previously found, there is nothing in the intrinsic record to support Roxane's proposed construction requiring that a GHB salt must be pre-formed externally before being dissolved and mixed in water.

It is a fundamental tenet of claim construction that reading limitations into claims constitutes legal error when those limitations are not found in the claim language. *See McCarty v. Lehigh Valley, R.R.*, 160 U.S. 110, 116 (1895) ("[W]e know of no principle of law which would authorize us to read into a claim an element which is not present . . ."). Ignoring this principle can result in a construction that is too narrow and devoid of any connection to the intrinsic record. *See, e.g.*, *Decisioning.com v. Federated Dep't Stores, Inc.*, 527 F.3d 1300, 1312 (Fed. Cir. 2008) ("Engrafting the claims with these limitations produces anomalous results, not supported by the specification or the claims themselves"). Roxane's proposed constructions are also wrong to the extent that Roxane is attempting to limit the scope of these claims terms to particular embodiments. The Federal Circuit has repeatedly held that it is improper to limit claims to the embodiments described in the specification. *See Phillips*, 415 F.3d at 1323-24; *Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986) ("This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification."); *see also Home Diagnostics*, 381 F.3d at 1358 (patentee is entitled to full scope of claims absent "a clear disavowal or contrary definition").

Here, Roxane has fabricated its proposed constructions in an attempt to support its non-infringement position. But Roxane cannot cite anything in the intrinsic evidence that supports its

proposed limitations. Thus, Roxane's constructions lack merit, both for failing to encompass the full scope of the claim term and for attempting to read nonexistent limitations into the claims. The Court should reject Roxane's proposal and hold that the term "admix" does not require construction.

2. "Contacting"

The disputed claim term "contacting" appears in claim 10 of the '203 patent. Claim 10 states (with emphasis on the disputed claim term):

> A method of rendering an aqueous medium comprising a salt of gamma-hydroxybutyrate resistant to microbial growth, said method comprising **contacting** a salt of gamma hydroxybutyrate with the aqueous medium, adjusting the concentration of the gamma-hydroxybutyrate salt in the aqueous medium to a final concentration of from about 310 to about 750 mg/ml, and adjusting the pH of the medium to a final pH of about 6 to about 9, so that the medium is chemically stable and resistant to microbial growth, wherein the medium does not contain a preservative.

The parties' proposed constructions are as follows:

"contacting"	
Jazz's construction	**Roxane's construction**
No construction necessary.	"to put or bring into physical contract or to physically touch two separate and distinct items"

Like "admix," the term "contacting" does not require construction. As discussed above, claim construction is not an obligatory exercise in redundancy. *U.S. Surgical*, 103 F.3d at 1568. This term consists of an ordinary English word that means just what it says. Nothing in the intrinsic record warrants departure from its well-understood meaning.

Here, Roxane's construction repeats what the term means and then improperly imports a limitation into the claim. Like with "admixing" above and "adding" in the previous *Markman* briefing, Roxane appears to be attempting to read in a limitation that solid gamma

hydroxybutyrate salt must be added to an aqueous solution. Specifically, Roxane seeks to add the phrase "two separate and distinct items" which lacks any support in the intrinsic record. Those words never appear in the patent specification or claims. Likewise, Roxane cannot point to any support in the intrinsic evidence to construe the term "contacting" in the manner it seeks. As a result, Roxane has failed to rebut the heavy presumption that "contacting" carries its ordinary meaning. *See Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1371 (Fed. Cir. 2007).

Roxane's construction also impermissibly ignores the context of the claims. *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1347 (Fed. Cir. 2009) ("proper construction requires consideration of the context of the rest of the term"). Here, the term "contacting" appears in a claim directed to "an aqueous medium comprising a salt of gamma-hydroxybutyrate." In an aqueous medium, a salt of gamma hydroxybutyrate exists in solution in water. It is not clear how a chemical is "separate and distinct" from the solution it is dissolved in as Roxane suggests it should be. Therefore, Roxane's construction should be rejected because it would render the claim in which it appears nonsensical.

Roxane appears to be attempting to add unsupported limitations to the term "contacting" to avoid infringement. This effort to engraft extraneous limitations into this term should be rejected. *See Decisioning.com*, 527 F.3d at 1312. Rather, the term contains words that are well understood and require no further construction. Accordingly, Roxane's proposed construction should be rejected.

B. The '306 Patent Family

The '306 and '302 patents claim methods of treating certain sleep disorders in patients with reduced dosages of GHB, when GHB is co-administered with valproate. The parties dispute one term in those patents, as discussed below.

1. "Concomitant"

The disputed claim term "concomitant" appears in claims 1, 3, 8, and 11 of the '306 patent and claims 1, 3, 5-8, 11, 13, and 19 of the '302 patent. Claim 1 of the '306 patent states (with emphasis on the disputed claim term):

> A method for treating a patient who is suffering from excessive daytime sleepiness, cataplexy, sleep paralysis, apnea, narcolepsy, sleep time disturbances, hypnagogic hallucinations, sleep arousal, insomnia, or nocturnal myoclonus with gamma-hydroxybutyrate (GHB) or a salt thereof, said method comprising: orally administering to the patient in need of treatment at least 5% decrease in an effective dosage amount of the GHB or salt thereof when the patient is receiving a **concomitant** administration of valproate, an acid, salt, or mixture thereof.

The parties' proposed constructions are as follows:

"contacting"	
Jazz's construction	**Roxane's construction**
"the administration of at least two drugs to a patient either subsequently, simultaneously, or consequently within a time period during which the effects of the first administered drug are still operative in the patient"	"administration of a drug product to a single patient either subsequently, simultaneously, or consequently within two weeks of administration of a second product"

"Concomitant" is explicitly defined in the '306 patent's specification:

> "Concomitant" and "concomitantly" as used herein refer to the administration of at least two drugs to a patient either subsequently, simultaneously, or consequently within a time period during which the effects of the first administered drug are still operative in the patient.

(Ex. 3, '306 patent at 8:37-41.) One of the most established principles of claim construction holds that when a patent applicant specifically defines a claim term in its description of the invention, that definition controls. *Phillips*, 415 F.3d at 1316 ("[T]he inventor's lexicography governs."). The Federal Circuit has consistently reversed claim constructions that do not follow

definitions set out expressly in the specification. *See, e.g.*, *Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1374 (Fed. Cir. 2006) (reversing district court's construction in favor of construction "as it is defined in the. . . patent specification"). The specification's explicit definition should be both the beginning and the end of the Court's inquiry on "concomitant."

By contrast, Roxane improperly ignores the patent's explicit lexicography. Roxane seeks to re-write the specification to add the word "single" to modify "patient" and to substitute the phrase "within two weeks of administration of a second product" for the phrase "within a time period during which the effects of the first administered drug are still operative in the patient." Roxane's inclusion of the phrase "single" should be rejected as an unnecessary exercise in redundancy. *U.S. Surgical Corp*, 103 F.3d at 1568. Roxane's proposed "within two weeks …" phrase appears to have been taken from examples listed in the specification of the timing for concomitant administration. (Ex. 3, '306 patent at 8:41-45.) But, examples are not part of constructions. *Tex. Instruments*, 805 F.2d at 1563 ("This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification."). Thus, this Court should adopt the inventor's stated lexicography as the construction for the term "concomitant."

V. CONCLUSION

For the foregoing reasons, Jazz respectfully requests that the Court adopt its proposed definitions of the disputed claim terms.

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